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Brenda Mallory, Esq.
Associate General Counsel
US Environmental Protection Agency
Office of General Counsel [2310A]
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Petition to Deny Registration Application for the Pesticide Product "Timber Treat" Under the Federal Insecticide, Fungicide, and Rodenticide Act.

Dear Ms. Mallory:

On behalf of Nisus Corporation (Nisus), we hereby petition the Environmental Protection Agency (EPA or the Agency) to deny the registration application that was recently filed by Turf Science Laboratories, Inc. (Turf Labs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registration of a pesticide product known as "Timber Treat," or to cancel the registration of that product if it has already been registered. Nisus files this petition pursuant to the following authorities: (i) EPA's regulations at 40 C.F.R. §152.99; (ii) the Petition Clause of the First Amendment to the Constitution of the United States; and (iii) the inherent authority to petition the Agency under FIFRA.

I. OVERVIEW

Turf Labs has submitted an application to register a termiticide product known as Timber Treat. We understand that Turf Labs seeks to register Timber Treat for use as a primary termiticide pre-treatment product, among other possible uses. Primary termiticide pre-treatment products are used primarily in connection with new construction and are intended to provide a long-term barrier to termites, to prevent infestation of the structure being built.

In order to register a termiticide product, or any other public health pesticide product, an applicant must provide EPA with data sufficient to demonstrate the efficacy of the product. In general, EPA requires this efficacy data to be generated on the specific

product to be registered. Consequently, efficacy data that is generated on one product generally cannot be utilized to support the registration of a different product with a different composition.

As far as we can determine, Turf Labs has not provided EPA with any efficacy data on Timber Treat in support of the product's registration application. Instead, Turf Labs seeks to support its Timber Treat application by citing efficacy data that Nisus previously submitted to EPA in connection with the registration of Nisus' registered termiticide pre-treatment product, Bora-Care® (EPA Reg. No. 64405-1). However, because Turf Labs' Timber Treat product has a different chemical composition than Nisus' Bora-Care® product, the efficacy data that Nisus has generated on Bora-Care® cannot be used to support Turf Labs' registration application. This is especially true with respect to the particular products at issue here, because a substantial body of scientific data demonstrates that with these types of products even slight differences in formulation can have a dramatic effect on product efficacy. Accordingly, Turf Labs should be required to submit its own efficacy data on Timber Treat in order to support the product's registration applications. Indeed, without such data, EPA cannot make the requisite finding of "no unreasonable adverse effects" that is required to register Timber Treat under FIFRA Section 3.

II. BACKGROUND

A. Authority to File Petition

EPA's regulations governing petitions to cancel or deny a registration provide that:

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

40 C.F.R. § 152.99. As demonstrated below, Nisus is an original data submitter, and in connection with the registration of its Bora-Care® product Nisus has submitted data that

Based on a search of the National Pesticide Information Retrieval System (NPIRS) conducted on March 14, 2007.

satisfy the efficacy data requirements applicable to primary pre-treatment termiticide products. Turf Labs has failed to provide data on its Timber Treat product to satisfy these same efficacy requirements, and the company cannot rely on Nisus' Bora-Care® data in lieu of providing its own data. Thus, Nisus' petition is well-grounded in the regulations at 40 C.F.R. § 152.99.

In addition to the specific rights provided to data submitters under 40 C.F.R. § 152.99, EPA has also recognized that the Petition Clause of the First Amendment to the United States Constitution provides a separate basis for petitioning the Agency to deny or cancel a registration. See Letter from J. Jones, Director Registration Division, Office of Pesticide Programs, USEPA to J. Wright and J. Liss (June 13, 2000). Finally, EPA has also acknowledged that FIFRA itself provides an independent right to petition the Agency to cancel a registration. Id. Accordingly, Nisus has adequate bases for filing this petition.

B. Nisus' Bora-Care® Product (EPA Reg. No. 64405-1)

Nisus' Bora-Care[®] product is an end-use product containing 40% disodium octaborate tetrahydrate (DOT) as the active ingredient. The product also contains a number of other components, including ethylene glycol and polyethylene glycol, in a proprietary formulation that is protected by patent.²

Bora-Care® was initially registered in 1990, solely for use as a wood preservative. Shortly thereafter, it was determined that the product is effective in killing a wide range of wood destroying insects, including termites. In addition, Bora-Care® was also demonstrated to be effective as a long-term barrier against termites (by preventing the insects from crossing treated wood to reach untreated wood). Accordingly, in 1992 Nisus obtained an amended registration for Bora-Care® for use as a termite pre-treatment at new construction sites; and in 1994 Nisus obtained another registration amendment allowing for Bora-Care® to be used as a two-foot barrier treatment. These amended registrations were required to be supported by extensive efficacy testing. The data submitted by Nisus include both laboratory tests showing that Bora-Care® is effective at killing termites, as well as long term (5-year) field data which demonstrate that Bora-Care® provides a long-term barrier to termites. These efficacy data include the following MRID numbers: 46343603, 45867401, 45841201, 46306701, and 43563603. Nisus has continued to

² Bora-Care[®] is covered by the following patents: U.S. Patent Nos. 5,104,664; 6,426,095; 6,630,174; 5,296,240; 5,460,816; and 5,645,828.

generate additional efficacy data to support and expand the pre-treatment use of Bora-Care[®].

B. Turf Labs' Timber Treat Product

It is our understanding that Turf Labs' Timber Treat product is (like Bora-Care®) an end use product intended for use as a primary pre-treatment termiticide and that Timber Treat (like Bora-Care®) contains 40% DOT as the active ingredient.³ However, despite the fact that Bora-Care® and Timber Treat contain a common active ingredient, it is our understanding that the product formulations for the two products differ substantially. Indeed, since the formulation of Nisus' Bora-Care® product is protected by patents, and since we presume that Turf Labs would not infringe on Nisus' patents, we conclude that the chemical composition of Timber Treat *must* differ substantially from Nisus' proprietary Bora-Care® formulation.

III. ARGUMENT

If an applicant intends to register a termiticide product (or another public health pesticide product), EPA has consistently required that the applicant provide efficacy data that is generated on the specific product to be registered. This policy is based on EPA's understanding that even small differences in formulation can significantly affect a pesticide product's efficacy. Moreover, with respect to the particular DOT products at issue here, a substantial body of scientific evidence demonstrates that slight variations in formulation can dramatically *reduce* product efficacy. Accordingly, consistent with EPA regulation and policy, as well as sound science, Turf Labs should be required to provide its own laboratory and field testing data in order to demonstrate the efficacy of its Timber Treat product. Furthermore, in the absence of such product-specific data, EPA cannot make the requisite finding of "no unreasonable adverse effects" necessary to permit registration of Timber Treat under FIFRA Section 3. Consequently, since Turf Labs has failed to provide the required efficacy data on Timber Treat, EPA should deny Turf Labs' registration application, or if the registration has already been granted, the Agency should cancel the product's registration.

Nisus has asked Turf Labs for information regarding the formulation and percentage DOT contained in Timber Treat; however Turf Labs has thus far refused to provide this information other than to asser that Timber Treat does not infringe Nisus' patents.

A. EPA Has Consistently Required Submission of Product-Specific Efficacy Data

EPA has long recognized that efficacy data are highly product-specific, precisely because slight differences in formulation can significantly affect product efficacy. Therefore, EPA has consistently taken the position that efficacy data, when required for registration, must be submitted for the specific formulation being registered. The Agency articulated this position as early as 1979, in the context of its final rule establishing regulations for conditional registration. There, with respect to disinfectant and rodenticide products in particular, the Agency explained:

For disinfectant products and bait formulations of rodenticides, efficacy data, when required, must be developed and submitted for the individual formulation proposed by the applicant. The applicant may not rely on, and need not offer to pay compensation for, data already in our files pertaining to similar formulations. It has been the Agency's experience, borne out by efficacy data submitted in the past and by enforcement actions, that efficacy data in the disinfectant and rodenticide bait areas cannot be transferred from one formulation to another, even though the formulations may be virtually identical. . . . Thus each individual product must be supported by its own efficacy data.

44 Fed. Reg. 27932, 27939-40 (May 11, 1979) (emphasis in original). Although this particular statement was ostensibly limited to disinfectant and rodenticide products, EPA has applied this policy more broadly, to all products for which efficacy data are required for registration.

Thus, for example, in the preamble to the Agency's 1984 final rule establishing data citation and compensation regulations, EPA explained that FIFRA's "mandatory data licensing" provisions generally permit a "me-too" applicant to support his registration application by citing previously submitted, non-exclusive use data. In addition, the preamble describes two different mechanisms by which a "me-too" applicant can cite previously submitted data: namely, the "cite all" method and the "selective" method. 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984). However, the Agency goes on to caution that there are a few types of data requirements, including efficacy data requirements, that a me-too applicant *cannot* satisfy by citing data that were previously

submitted by another registrant; and, to satisfy these requirements, the me-too applicant must submit data that is specific to his own particular product. As the Agency explains:

Certain data requirements must be satisfied by the submission of data that are unique to the applicant's own product. These are primarily requirements for product composition, efficacy, and certain acute toxicity data.

Id. (emphasis added).

Probably the most recent articulation of the Agency's policy of requiring product-specific efficacy data is found in EPA's new procedural regulations for registration review. 71 Fed. Reg. 45720 (Aug. 9, 2006). In the preamble to the final rule, EPA discusses the possibility that the registration review process will identify additional data requirements needed to support continued registration of a pesticide. The Agency explains that most of these data needs will be generic; in other words, they can be satisfied by data generated on the active ingredient, rather than on specific product formulations. However, EPA goes on to acknowledge that certain types of data, including efficacy data, will need to be generated on a product-specific basis – especially where there is a difference in product formulation. Id. at 45729. The Agency explains that:

During the registration review of a public health pesticide, the Agency would determine whether to continue to base the product's registration on existing product efficacy data. The Agency may ask for new product efficacy data if the product's composition has changed so that existing data no longer support the current composition of the product . . . or there is information suggesting that the formulation might not be efficacious as claimed.

Id.

Finally, EPA's longstanding requirement for product-specific efficacy data is reflected in the Agency's regulations at 40 C.F.R. Part 158, which outline the basic data requirements for registration under FIFRA. The efficacy data requirements are set out in a data table at 40 C.F.R. § 158.640, which identifies categories of pesticides for which efficacy data are required. Importantly, for each and every category of pesticide listed in the table, the required test substance is listed as "EP*" – which, as explained in a footnote

to the table, signifies that the efficacy data must be generated using the specific product sought to be registered. Equally important, if EPA had intended to allow applicants to rely on efficacy data generated on other products – even products that are "substantially similar" to the applicant's product – the Agency would have listed "TEP" as the required test substance (signifying a "typical end-use product"). EPA did not do so; deciding instead to require product-specific efficacy data for all categories of public health pesticides specified in the regulations.

B. Testing Demonstrates that Even Slight Differences in the Formulation of DOT Products Can Significantly Affect Product Efficacy

With respect to Turf Labs' Timber Treat product in particular, the absolute need for product-specific efficacy data (and the inappropriateness of relying on Bora-Care® efficacy data) are underscored by a significant body of scientific evidence which demonstrates that slight differences in the formulation of DOT termiticides can have a significant effect on product efficacy.

For example, one study compared the oral toxicity of three different borate products (two of which contain the exact same active ingredient, disodium octaborate tetrahydrate). See M. Tokoro and S. Nan-Yao, Oral Toxicity of TIM-BOR, Bora-Care, Boric Acid and Ethylene Glycol against the Formosan Subterranean Termite and the Eastern Subterranean Termite (1993) (included here as Exhibit 1). The study found that Bora-Care (which includes both short- and long-chain glycols in its formulation, along with DOT) was substantially more toxic to termites than DOT alone or boric acid. Thus, the Tokoro study provides compelling evidence that for products containing borate (and DOT in particular), efficacy against termites is highly dependent upon the specific product formulation.

Another recent study, conducted by the College of Agricultural and Environmental Sciences at the University of Georgia, yields a similar conclusion. In a January 11, 2005 report to the Structural Pest Control Commission (included here as Exhibit 2) the researchers reported on the results of efficacy testing conducted on a termiticide product called Shellgard, which contains DOT and a different glycol matrix than Bora-Care®. The study found that in a 5-year efficacy trial, the Shellgard product "was *not* effective as a barrier at protecting untreated boards using standard ASTM

⁴ Specifically, for termites the LD_{50} of Bora-Care[®] was found to be 256.2 μ g/g AI, while the LD_{50} for DOT alone was 408.2 μ g/g AI and the LD_{50} for boric acid alone was 560.2 μ g/g AI. See Exhibit 1 at p.5.

ratings." Exhibit 2 at p.4 (emphasis added). In contrast, Bora-Care® was tested using an equivalent 5-year efficacy testing protocol, and Bora-Care® was demonstrated to provide an effective long-term barrier against termites. (See Exhibit 3, attached hereto.) Shellgard and Bora-Care® are both DOT products; however Shellgard contains a different glycol matrix in its formulation, while Bora-Care® contains two very specific glycols at specific ratios. Again, these data demonstrate that for DOT products in particular, a minor formulation difference can result in dramatic reductions in efficacy.

C. EPA Cannot Make the Requisite Finding of "No Unreasonable Adverse Effects" Without Product-Specific Efficacy Data on the Timber Treat Product

Before EPA can register a pesticide product, the Agency must determine, based on the data provided for the product, that "the product will perform its intended function without unreasonable adverse effects on the environment." FIFRA Section 3(c)(5); 7 U.S.C. § 136a(c)(5). Similarly, for conditional registrations the Agency must find that registration of the product "will not significantly increase the risk of any unreasonable adverse effect on the environment." FIFRA Section 3(c)(7); 7 U.S.C. § 136a(c)(7).

With respect to termiticide products, EPA has indicated that long term (5-year) efficacy data are essential to evaluating whether a primary pre-treatment termiticide poses an "unreasonable adverse effect on the environment." Specifically, in PR Notice 96-7 EPA states as follows:

The Agency believes that registration of a product demonstrating less than five (5) years of efficacy for control of termites is generally not appropriate from a safety or efficacy standpoint, considering the costs of treatment and the potential damage that could occur. The Agency does not believe that the homeowner should be subjected to such costly protection as would occur with products that are only efficacious for one year. Such products could, quite possibly, pose unreasonable adverse effects to the environment and/or humans because of higher risks than longer-acting alternatives. The more frequent treatments required could result in greater exposure and risk, or lower benefits, because of being less effective if not retreated, or more expensive if retreated.

PR Notice 96-7 at 2. Thus, for a primary pre-treatment termiticide such as Timber Treat, long term efficacy data for the product is necessary to evaluate whether the product may result in "unreasonable adverse effects" on the environment.

Accordingly, without reliable efficacy data on the specific Timber Treat product formulation sought to be registered (and, in particular, 5-year efficacy data for that formulation), EPA cannot make the requisite determination of "no unreasonable adverse effects" necessary to register the product under FIFRA Section 3.

IV. CONCLUSION

For the reasons described above, Turf Labs cannot rely on Bora-Care® efficacy data to support Turf Labs' application to register Timber Treat. Instead, consistent with EPA regulation and policy, as well as sound science, Turf Labs should be required to provide its own product-specific laboratory and field testing data in order to demonstrate the efficacy of its Timber Treat product. Furthermore, in the absence of such product-specific data, EPA cannot make the requisite finding of "no unreasonable adverse effect" necessary to permit registration of the products under FIFRA Section 3.

Therefore, since Turf Labs has failed to provide the required efficacy data on Timber Treat, EPA should deny Turf Labs' registration application, or if the registration for Timber Treat has already been granted, the Agency should cancel that registration.

Respectfully submitted,

Warren U. Lehrenbaum

Counsel for Nisus Corporation

Attachments

cc: Dr. Jeff Lloyd (Nisus)

Richard Gebken (EPA-PM-10) (by hand delivery)

John F. Wright (registration agent for Turf Labs) (by certified mail)

THE INTERNATIONAL RESEARCH GROUP ON WOOD PRESERVATION

Section 1

Biology

Oral Toxicity of TIM-BOR®, BORA-CARE™, Boric Acid and Ethylene Glycol against the Formosan Subterranean Termite and the Eastern Subterranean Termite

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Oral Toxicity of TIM-BOR*, BORA-CARE™, Boric Acid and Ethylene Glycol against the Formosan Subterranean Termite and the Eastern Subterranean Termite

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Abstract

Oral toxicities (LD₅₀) of boric acid, TIM-BOR[®] (disodium octaborate tetrahydrate: DOT) and BORA-CARETM (40% DOT in ethylene glycol) and ethylene glycol (ca. 80% monoethylene and ca. 20% polyethylene glycol) were estimated. Oral toxicities of BORA-CARETM were significantly higher (LD₅₀: 256.2 μg/g DOT and 304.9 μg/g BAE) than TIM-BOR[®] alone (LD₅₀: 408.2 μg/g DOT and 485.7 μg/g BAE); indicating a potential synergism of DOT by ethylene glycol in BORA-CARETM.

Introduction

Although the basis of their toxicity is not well understood (Williams et al. 1990), boric acid and boron salts are toxic to termites (Randall et al. 1934; Reierson 1966; Williams & Amburgey 1987; Grace 1990b; Grace & Abdallay 1990). TIM-BOR® (disodium octaborate tetrahydrate: DOT, Na₂B₈O₁, 4H₇O) and BORA-CARE™ (40% DOT in ethylene glycol) are two borate products, marketed for treating wood by brushing or spraying onto the wood surface. The ability of ethylene glycol solution in BORA-CARE™ increased the solution concentration for practical used (20% solution for BORA-CARE™ vs. 10% solution for TIM-BOR®). It is also claimed that BORA-CARE™ may be more toxic than TIM-BOR® against termites because of synergism by the ethylene glycol solution. However, no data are available that address this claim. Data provided by Grace et al. (1992) indicated that the glycol solvent carrier did not contribute significantly to the toxicity of the DOT/glycol mixture.

To determine if ethylene glycol enhanced toxicity of TIM-BOR® against termites, oral toxicity of ethylene glycol, TIM-BOR®, BORA-CARE™ and boric acid need to be determined. Estimating toxicant doses (μg/g) required to kill termites by ingestion, however, has been rarely been achieved because of the difficulty in accurate measurement of food consumption by termites. Consequently, the oral toxicity of a toxicant reported in previous studies was usually expressed as a lethal concentration (LC₂₀), namely the toxicant concentration in the feeding medium (Su & Scheffrahn 1988, Grace 1990), instead of a lethal dose (LD₂₀). LD₂₀s of slow-acting toxicants were applied topically (Su & Scheffrahn 1988, 1991a). Recently, we designed a procedure to accurately estimate the toxicant dose consumed by termites to estimate the LD₂₀ (μg/g) of slow-acting toxicaot against termites (Su et al. in press).

The objectives of this study are to estimate the oral toxicities (LD₅₀) of boric acid, TIM-BOR[®], BORA-CARETM, and ethylene glycol solvent, and to examine the potential synergistic effects of the ethylene glycol in BORA-CARETM.

Materials and Methods

Chemicals tested included TIM-BOR, boric acid (U.S. Borax Research, Anaheim, CA), BORA-CARETM and ethylene glycol solvent (Nisus corporation, Knoxville, TN). Nile Blue A (Aldrich chemical Company, Inc., Milwaukee, WI) also was used to dye the termite.

Termites were collected from three field colonies each of the Formosan subterranean termite, Coptotermes formosanus Shiraki, and the eastern subterranean termite, Reticulitermes flavipes (Kollar), in southeastern Florida as described by Su & Scheffrahn (1986). Mean body weights of field collected termites were determined for each colony-species combination by weighing 10 groups of 50 individuals.

Before testing, termites were placed in petri dishes (9.0 by 1.5 cm) provisioned with a stainless-steel screen and starved in an environmental chamber at $28 \pm 1^{\circ}$ C and 100% RH for 24 hours (*R. flavipes*) or 48 hours (*C. formosanus*). Fine sawdust (> 40 mesh) of spruce (*Picea* sp.) was

dried in a desiccator for 72 hours and weighed before mixing with toxicant. Five hundred mg sawdust was homogeneously mixed with aqueous solutions of each toxicant and 0.05% (wt/wt) Nile Blue A to yield the desired toxicant concentrations (wt/wt fresh bait).

Fifty starved termites were weighed $(\pm 0.1 \text{ mg})$ and placed in a plastic petri dish (5.0 by 1.5 cm) containing a pre-weighed amount (approximately 3 mg) of diet $(\pm 0.1 \text{ mg})$. The bottom of each petri dish was previously etched with sandpaper to provide traction for the termites during the test period. A preliminary test using toxicant concentrations of 0, 100, 1000, 10,000 and 100,000 ppm (wt Al/wt fresh bait) was conducted to estimate the effective ranges (final mortality between 0-100% at 14 day). Five to ten concentrations within the effective range were chosen for testing. The feeding units were held at $28 \pm 1^{\circ}$ C until all the diet was consumed by the group of 50 termites. Approximately 3 mg of diet was usually consumed within 3 - 4 hours.

In previous feeding studies (Su & Scheffrahn, 1988; 1991) termites were typically placed upon diet, such as treated filter papers, allowing an unknown amount of toxicant to be absorbed through termite integument. In this study, the volume of the diet was so small that only termites' mouthparts and antennae touched the diet. This arrangement reduced topical absorption of toxicants by termites. Termites (presumably in the molting process) are known to go through a fasting period for several days. Termites that were actively feeding turned blue from the Nile-Blue dye in the diet. The fasting individuals were identified by the absence of visible dye and were excluded from the units.

The oral dose was calculated from the total amount of active ingredient in each petri dish, the amount of diet eaten, and the total biomass of termites that consumed the diet. After feeding, termites were transferred to a petri dish (5.0 by 1.5 cm) provisioned with moistened filter paper disks. Five C. formosanus soldiers were added to each C. formosanus dish and one R. flavipes soldier were added to each R. flavipes dish to approximate colony soldier proportions. Dishes containing termites were stored in an environmental chamber at $28 \pm 1^{\circ}$ C. Dead or moribund workers were recorded and removed from each unit daily up to 14 days. Mortality data at the 14th day were subjected to a probit analysis (SAS Institute 1985) to estimate the oral LD₂₀ ($\mu g/g$). The potential synergistic effects of the ethylene glycol were determined by comparing LD₂₀s of these compounds.

Results and Discussion

Mortality of termites in untreated control after 14 days was 4.4% for *C. formosanus* and 13.2% for *R. flavipes*. Mean mortality of the termites fed on medium contains ethylene glycol after 14 days was 8.2% for *C. formosanus* and 18.1% for *R. flavipes*. Because of the insignificant mortality, the LD₂₀ value of the ethylene glycol for both termite species couldn't be estimated. The highest concentration of ethylene glycol used was 27% (w/w).

Results of the oral toxicity test are shown in Table 1. When the 60% inert ingredient (ethylene glycol) is included in the estimate, a comparison of LD50 value for BORA-CARE™ appeared higher than TIM-BOR®; 640.5 and 238.7 μg/g for C. formosanus and R. flavipes, respectively. LD₂₀ values based on active ingredient (AI), which is DOT for both BORA-CARE™ and TIM-BOR®, indicated that BORA-CARE™ is approximately 1.5-fold more toxic than TIM-BOR® for both termite species. Because ethylene glycol alone did not cause significant mortality, the presence of ethylene glycol in BORA-CARE™ appeared to synergize DOT (active ingredient of BORA-CARE™) toxicity against termites. The reason for this synergism is unknown. A comparison of LD₂₀ values based on BAE (boric acid equivalent) indicated that boric acid is the least toxic for both termite species. Although BAE is a standard unit for comparison of efficacy among borate compounds, our results indicated that BAE may not be an accurate representation of efficacy for borate compounds against termites.

Table 1. Oral toxicity of boric acid (BA), TIM-BOR® (TB), BORA-CARE™ (BC) and ethylene glycol (EG) against C. formosanus and R. flavipes.

	(m -) (-9					
	***	İ			LD ₅₀ (95% FL)	d Morrey de Address
Comp.	Worker Wt. Comp. (mg, X ± SE)	Z	Slope ± SE	(8/8n)	(μg/g A1) ^σ .	(μg/g BAE) ^b
				C. formosanus		
Z A	3.55 ± 0.21	1273	3.91 ± 0.68	560.3 (415.8 - 662.9)	560.3 (415.8 - 662.9)	560.3 (415.8 - 662.9)
i f	3.25+0.18	2062	3,35 ± 0.24	408.0 (354.4 - 457.1)	408.2 (354.4 - 457.1)	485.7 (354.4 - 457.1)
. J	3.31 ± 0.20	1583	4.72 ± 0.51	640.5 (539.3 - 724.0)	256.2 (215.7 - 289.6)	304.9 (215.7 - 289.6)
EG C	3.35 ± 0.29	1018	0.58 ± 0.63	v,	•	1
				R. flavipes		
A A	1.97 ± 0.03	1584	12.83 ± 1.41	369,8 (350.8 - 386.9)	369.8 (350.8 - 386.9)	369.8 (350.8 - 386.9)
TB	2.05 ± 0.02	1987	3.93 ± 0.39	141.0 (120.1 - 158.5)	141.0 (120.1 - 158.5)	167.8 (142.9 - 188.6)
BC	2.02 ± 0.03	1583	4.89 ± 0.97	238,7 (176.3 - 279.7)	95.5 (70.5 - 111.9)	113.6 (83.9 - 133.1)
Ħ.	1,91 ± 0.04	956	1.50 ± 0.78	o,	4	
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DOT is Al for TB and BC
 BAE: boric acid equivalent

c no significant mortality

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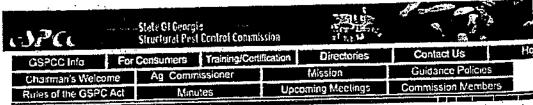
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MINUTES OF THE STRUCTURAL PEST CONTROL COMMISSION

The Georgia Structural Pest Control Commission met at 10 AM, in Room 103 of Conner Hall on the University of Georgia Campus on January 11, 2005. Present were the following members:

Dr. Dan Suiter Tom Diederich Jimmy Allgood, Chair Jeff Gary Jim Harron, Vice Chair Ann Hyde

Also in attendance were representatives of GPCA, CPCO, other members of the pest control industry, representatives of the Department of Entomology of the University of Georgia and Derrick Lastinger and Jason Tripp representing the Department of Agriculture.

Motion was made by Mr. Diederich to approve the minutes of the December meeting as amended, seconded by Mr. Gary and passed by the Commission.

The Commission approved the following companies:

- 1. Cooks Pest Control Atlanta
- 2. BACO Cumming
- 3. Awesome Pest Control Canton

The Commission approved the following company pending name change:

1. Ever Ready - Byron

: Dr. Ray Noblet of the University of Georgia welcomed the Commission and presented an update of the Entomology program at the University. He indicated that it is his desire to work closely with the members of the Commission and the industry. He also indicated that Mr. Corey Arnold of Peachtree Pest Control will be assisting in student recruitment.

Dr. Brian Forschler provided an update on his research which included:

- 1. identification of termite protists
- 2. 3rd year of a study involving the Whitmire Micro-Gen system utilizing a molecular marker to verify colony elimination
- 3. 3rd of a study on residual efficacy of non-repellent termiticides
- 4. reticulation systems for distribution of termiticides
- 5. study of borates for termite control in wood
- 6. bioassay of transfer of non-repellent termiticides

Dr. Forschier urged the pest control industry to stop trying to "dumb down"





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termite control and to stop looking for the next "silver bullet" for termite

Dr. Suiter provided an update on his research and work which included:

1. continued study of various ant species

2. various non-repellent insecticides for ant control

3. development of several new bulletins including one for identification of Formosan termites to be used by pest control technicians

4. update on the status of the 20 Formosan termite sites found in Georgia

Mr. Allgood thanked Drs. Noblet, Forschler and Suiter for helping to advance the pest control industry in Georgia. He also noted that Mr. Rick Bell of Arrow Exterminators is working to secure additional funds on the national level for suppression of the Formosan termite in Georgia.

The Commission discussed the proposed emergency Rule change. Mr. Harron reviewed a letter he sent to the Commission members and members of the pest control industry concerning the Form II. He stated that the Form II may not be used to bypass the minimum standards and that the use of the Form II for a limited soil treatment is not a legal or acceptable method to achieve a limited soil treatment.

Mr. Allgood indicated that the Commission had received a letter from Mr. Robert Moss, attorney for CPCO of Georgia. He read part of the letter which stated that CPCO intended to "... take all appropriate legal action to challenge the implementation of the proposed regulations, should the Georgia Structural Pest Control Commission enact said Limited Treatment Regulations on an emergency basis".

After discussion Mr. Gary made a motion not to pursue the adoption of emergency Rules but instead to proceed via the normal adoption process, seconded by Mrs. Hyde and passed by the Commission.

Mr. Allgood indicated that the Rule making process can be lengthy and will involve more than just limited soil treatment. Mr. Harron indicated that the misuse of Form II's is now an enforcement priority for the Department of Agriculture.

Mr. Steve Arnold of Peachtree Pest Control informed the Commission about his work with the Georgia Department of Community Affairs (DCA) on the issue of foam construction materials. He indicated that this is a very complex issue to address to the point that each county may have special requirements and/or exceptions to the building codes. Mr. Jeff Williams of CPCO indicated that the Georgia General Assembly may fund building inspectors to help enforce building codes during this session. All parties agreed that the best course of action at this time is to continue to work with DCA on these issues.

Mr. Lastinger updated the Commission on the reapproval of courses and instructors. He stated that there are 125 instructors approved along with 600 NII 09419

courses.

The Commission discussed approval for "category 5" trainers; people who want to be approved but do not meet any other requirements. These people will appear before a Commission appointed committee to present a topic. Mr. Lastinger inquired as to what will happen if an applicant does not meet with the approval of the committee. The Commission elected to offer an option to appear before the entire Commission if they are not approved by the committee.

Mrs. Fran Webber of CPCO expressed her thanks to Mr. Lastinger in working with CPCO on solving problems that occurred with the first use of the KTracks system.

Mr. Aligood thanked everyone for their attendance and interest in the work of the Commission. He indicated that he feels the Commission, despite some criticism, is pro-active in dealing with changes that occur in the industry. Further that the interests of the Commission have to include both the consumer and the industry.

Jimmy Allgood, Chairman

Commissioner Tommy Irvin, Sec.

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URBAN PEST CONTROL PROGRAM HOUSEHOLD AND STRUCTURAL ENTOMOLOGY COLLEGE OF AGRICULTURAL AND ENVIRONMENTAL SCIENCES UNIVERSITY OF GEORGIA ATHENS, GEORGIA

DATE OF REPORT TO COMMISSION: January 11, 2005

PROGRESS REPORT:

Research on the protist species found in subterranean termites illustrated that observation and enumeration of these necessary symbionts was enhanced by using a nitrogen-sparged media that is an improvement over previously published techniques. We were able to identify 2 new species of protist in Reticulitenes virginicus and 7 new species in R. hageni as well as demonstrate that termite species can be identified using the proportion of protist species found in the must numerous caste—the worker termite. This technique, which we outlined in detail for the first time in the scientific literature, will allow termite species identification in cases when either of the traditional taxonomically diagnostic castes (alates and soldiers) are absent at an infestation site.

Research on termite bait efficacy using the Whitmire Micro-Gen system are in their third year at 6 sites using molecular markers to verify colony elimination. The bait sites, following bait consumption, bave provided 2+ years of inactivity while the control sites continue to record high levels of termites activity. This is the first study using a commercial termite bait product to use control sites and constitutes the only study where the scientific method has been applied to measuring termite bait efficacy. We are in the third year of a field study examining the residual efficacy of the newly registered termiticide containing thiomethoxiam - the information to date demonstrates that the residual activity declines each year post-application. Tests with several reticulation systems were conducted and demonstrated that none of the systems tested can provide consistent, continuous coverage of soil under a slab. This point relates to the fact that these systems depend on point sources (holes along tubes) to deliver termiticide and that they may be better suited for protecting perimeter, penetrations, or other critical areas versus full coverage under slabs. Field tests with the borate product from Perma-Chink, Shell Guard, showed it was not effective at protecting untreated boards using standard ASTM ratings. However, these tests are continuing because we believe this and similar produces that allow termite access across treated lumber may - in the long term - be effective at preventing economically significant damage. This study will serve as a test case to challenge 'traditional' termite field trial efficacy standards that could be eliminating effective control tactics from the registration process.

Laboratory bloassays using non-repellent chemistries have illustrated how transfer of these toxicants occurs and highlights the unpredictable nature of this phenomenon in the field. Termites can be killed by a non-repellent termiticide by obtaining a dose through cuticular contact or by ingestion. Termites manipulating treated soil can obtain a lethal dose by swallowing some of the chemistry as it releases from the soil or they can get a

lethal dose from touching the treated soil as they dig through it. Termites not involved in tunnel construction/maintenance can pick up a lethal dose by contacting treated soil while moving through the gallery system, by touching/bumping other dermal-exposed termites or by grooming previously exposed termites. Dose/mortality curves were generated for all the currently registered non-repellent chemistries and they show that some chemistries are less toxic by the oral route than by contact. This means that all of the aforementioned factors play a role - along with bioavailability, termiticide concentration, and amount of contact with treated soil - in toxicant transfer resulting in field results that may or may not demonstrate transmission beyond the point of application.

EXPENDITURES:

During the 2003 calendar year, over \$145,000 was spent in salaries and staff benefits for permanent and temporary personnel in Athens and Griffin attached to this program. These funds, as well as an additional \$75,000, for supplies and equipment were provided entirely by extramural sources. The funds from the State Structural Pest Control Commission research fees provided for salary and benefits for a research scientist position at \$35,000 and three student part-time workers at \$10,000 in Griffin and Athens respectively.

PLANNED RESEARCH:

Over the next 2 years, we will continue to address the following critical research areas: (1) biology of termites including population dynamics and colony structure; (2) physiological measures of termite vigor/health; (3) efficacy and development of baits and new soil chemistries as termite control strategies; (4) termite behavior involving task allocation, and movement within the colony, and: (5) termite species identification using morphology, protozoan communities, agonistic behavior, and DNA markers.



FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

DIVISION OF AGRICULTURAL ENVIRONMENTAL SERVICES

BUREAU OF PESTICIDES

SCIENTIFIC EVALUATION SECTION

TERMITICIDE EFFICACY REVIEW FOR BORA-CARE WOOD TREATMENT (DISODIUM OCTABORATE TETRAHYDRATE)

> DAVIS H. DAIKER, PH.D. JANE FERGUSON FOOS

FEBRUARY 23, 2006

This review is a summary of the most current technical information available on the product or active ingredient reviewed in an attempt to address present or future issues with regard to the efficacy of the product. Conclusions drawn in this review are tentative and based on current research supplied by the registrant. This review includes both quantitative and qualitative information. The Scientific Evaluation Section welcomes comments and discussion of these issues.

This review is not an endorsement of any brand or active ingredient named in the document. Mention of a trademark or a proprietary product does not constitute a guarantee or a warranty of the product by Florida Department of Agriculture and Consumer Services, and does not imply its approval to the exclusion of other products that may also be available.

The author(s) can be reached by mail at:

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Web Site: http://www.flaes.org/pesticide/scientificevaluation.html

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Introduction

Under the Termiticide Efficacy Rule (5E-2.0311 F.A.C.), adopted in March 2003, registrants marketing a product for prevention of subterranean termite infestation in new construction are required to submit data demonstrating the effectiveness of their product. Specifically, registrants must provide data demonstrating that their product can effectively prevent subterranean termite infestation of new construction for a period of no less than 5 years.

The Nisus Corporation has submitted efficacy data to the Scientific Evaluation Section (SES) for evaluation under the guidelines set forth in 5E-2.0311 F.A.C. Specifically, for a woodapplied, preventive treatment, the Rule requires the submission of data from both field efficacy studies and structural efficacy tests conducted with the product applied according to label directions. The following is a summary and evaluation of the submitted efficacy data in support of the following product:

(40% disodium octaborate tetrahydrate) (EPA Reg. No. 64405-1) Bora-Care

Label Directions

Bora-Care is a wood applied product labeled for use as a stand-alone preventive treatment of new construction for protection against subterranean termite infestation/damage to structural wood. The label recommends a 1:1 dilution of Bora-Care be applied to the point of wetness at the point during construction where the greatest access to all wood members is available. This refers to the point where structural wood and sheathing has been installed, but prior to installation of insulation, electrical wiring and mechanical systems. Bora-Care should be applied to all structural wood in a 24-inch, uninterrupted band beginning with the sill area and extending upwards onto the sheathing. On crawlspace and foundation walls, Bora-Care should be applied in a 24-inch, uninterrupted band both horizontally and vertically to all structural wood, including sills, plates, floor joists, piers, girders, subfloors and all structural wood above foundation walls and piers. Following the most recently registered label, which was approved in the State of Florida, Bora-Care must also be applied to plumbing penetrations, bath traps, slabs and foundation walls of crawlspaces and basements to create a continuous vertical and horizontal barrier.

Field Studies

Nisus Corporation has submitted the results of the June 1996, December 1996, and December 1997 field inspections from field tests conducted in Mississippi at the Forest and Wildlife Research Center, Mississippi Forest Products Laboratory, Mississippi State University (Starkeville, MS). These studies were initiated in October 1991. Therefore, these inspection results represent the field evaluations 5 years after product treatment and therefore, are applicable to satisfy the Rule. The trials were conducted in a joist test design, which is appropriate to assess the ability of Bora-Care to deter termites from tunneling over treated wood, and more importantly protect wood that was not treated with product.

The following table presents the test groups and number of joist tests in each treatment.

Group	No. of units
Untreated/old wood	15
Untreated/new wood	15
Treated/old wood	15
Treated/new wood	15

The treated joist test units are wooden boxes comprised of wood that has been treated with Bora-Care that form the uprights of the box. This treated wood sits atop cinder blocks which are in direct contact with the soil. The untreated, bait-wood is then placed on top of the treated wood. With this design, termites must tunnel over treated wood to access the untreated wood or feed on the treated wood. For "control" test units, all wood in the test unit is untreated. In addition, within each joist unit, two untreated, wooden stakes were inserted into the soil to document termite pressure in the area. The influence of weather was prevented by covering the unit with a plywood box.

Bora-Care was applied to the treated wood at a 1:1 dilution to the point of runoff, as prescribed by the label. Inspections were made every 6 months for the first 24 months, and then annually thereafter. Nisus Corporation submitted two progress reports containing the data from the June 1996, December 1996 and December 1997 inspections.

Evaluation Procedure

"Passing Criteria" for Individual Joist Tests- As stipulated in the Rule, at each evaluation, an individual plot test will be considered "passing" if the untreated bait receives a USDA Forest Service wood damage score of 0 (no damage) or 1 (surface etching) or an ASTM scale rating of 9 or higher using ASTM D1758-96, in at least 90% of field trials for a minimum of five years.

"Passing Criteria" for the Product- For the product to be considered passing under the Rule, 90 percent of the joist tests must receive a passing score at each evaluation for a minimum of 5 years.

Results

FDACS began by evaluating the termite pressure in the area by reviewing the results from the wooden stakes installed within each joist unit. During the June 1996 evaluation, greater than 90% of the wooden stakes showed termite damage (Table 1) and several of the stakes contained live termite specimens. The species was not identified in the progress report. Wood damage ratings were also very low (Table 1), indicating significant damage. This high percentage of attack rate (90%) on the monitoring stakes suggests that the termite pressure in the area is sufficient. This is again discussed further in this section.

With regard to the evaluations of the tunneling/damage to the treated wood and bait-wood, Table 1 summarizes the frequency and degree of damage for the two control groups and the two treated groups. In order to simplify evaluating the results of the field joist tests with respect to the performance criteria of the Rule, the two control groups were pooled and the two treated groups were pooled to increase the number of test units per group to 30.

Table 1. June 1996 evaluations

able 1. Julie 1990 evaluation	Monitorir	ng stakes	Baitwo	ood
Treatment	Mean rating	% attacked	Mean % wt. loss	% attacked
Untreated/old wood (n=15)	1.7	96.7	13.3	40 (6 of 15)
Untreated/new wood (n=15)	2.7	90	15.8	26.7 (4 of 15)
Treated/old wood (n=15)	3.2	90	0	0
Treated/new wood (n=15)	2.4	93.3	41.1	13.3 (2 of 15)

As Table 1 indicates, bait-wood from 10 of 30 (33.3%) untreated, control joist units showed damage. In addition, 6 of the 10 joists had damage so significant that the author stated it was "...so badly eaten, little sound wood is left", although no wood damage scores were reproted. In the treated group, bait-wood from 2 of 30 treated tests showed damage. However, investigators observed that in the treated units showing damage to the bait-wood, there was no tubing across treated wood to gain access to the baitwood. Rather, the termites gained access to the baitwood by tunneling through the monitoring stake. If these two "failures" are not considered, 0 of 28 treated joist tests failed (0%). Further commentary on this is given in the following "Conclusion" section.

Table 2. December 1996

able Z. December 1990	Monitorir	ng stakes	Baitwo	Baitwood							
Treatment	Mean rating	% attacked	Mean % wt. loss	% attacked							
Untreated/old wood (n=15)	6.3	70	11.5	13.3 (2 of 15)							
Untreated/new wood (n=15)	7.1	76.7	11	6.7 (1 of 15)							
Treated/old wood (n=15)	5.6	80	0	0							
Treated/new wood (n=15)	5.6	86.7	0	. 0							

In the December 1996 inspection, which represents a complete five years since installation, a high frequency of attack and damage to the monitoring stakes was observed (Table 2). However, the frequency of attack on the monitoring stakes appeared slightly reduced, relative to the June inspection. This is presumably a function of reduced time since the prior inspection. Recall, the last inspection before the December 1996 inspection was in June of that year, whereas the last inspection prior to the June 1996 inspection occurred in October of 1993. This difference in time between inspections would logically allow for more time for foraging, tunneling, feeding and damage. With regard to the bait-wood, 3 of the 30 untreated units exhibited damage to the bait-wood, while no tunneling across any treated wood or damage to the bait-wood in the treated units was observed.

Conclusion

Although the Mississippi State University report did not provide the ASTM scores for the individual pieces of bait-wood evaluations, as required by the Rule, SES feels this data can be applied to the criteria of the Rule if we assume any damage to bait-wood is equal to a failing score. Based on this assumption and these data, Bora-Care has satisfied the performance criteria for the field efficacy studies. Specifically, greater than 90% of the treated test units showed no evidence of tubing over treated joist-wood or damage to the treated joist- or baitwood.

Building Tests

In addition to the submission of efficacy data from field studies, Section (1)(c)3 of the Rule requires that for wood-applied products, registrants must demonstrate efficacy in structures that have been treated with their product as a stand-alone treatment.

In lieu of developing a new study to evaluate the effectiveness of Bora-Care, Nisus Corporation and Terminix International collaborated to collect data from existing structures to meet the efficacy requirements set forth in 5E-2.0311 F.A.C. In 2003, 30 single-family, residential structures were randomly selected from a pool of 98 structures. The pool of 98 structures met the following criteria:

Free of infestation at the time of treatment.

2. Treated in the year 2000.

3. Treated with Bora-Care alone, according to label directions, and were covered

under a damage/repair warranty.

4. Located in either Dothan, Alabama or Gulfport, Mississippi, where environmental conditions and resident termite species are comparable to those in Florida. Therefore, these test conditions are acceptable to satisfy Section (2)(c)1 of the Rule.

In 2004, FDACS requested that Nisus document the termite pressure in the area around each. structure by installing wooden stakes within 10 feet of each structure. Nisus installed two wooden stakes on opposite sides of each structure. Nisus' compliance with FDACS' request was voluntary since the structures being studied were treated prior to adoption of the efficacy Rule and are not required to demonstrate termite pressure within 10 ft. of the structure (Section (2)(c)9). Building tests conducted after the adoption of the efficacy Rule are required to demonstrate termite pressure within 10 ft of the structure for minimum of 10 of the 25 structures tested.

Study structures were treated in 2000 and inspected annually by Terminix International through the 2003 annual inspection. In 2004, Terminix International conducted the annual structural inspections using an upgraded inspection form. In 2005, Nisus Corporation and Terminix International conducted the final inspections using the Nisus inspection form. The fifth year inspections included the use of moisture meters and a boroscope in the case of one infested structure.

Evaluation Procedure

"Passing Criteria" for Individual Structure- By Rule, a structure "passes" if it remains free of subterranean infestations within 5 years following treatment of the structure.

"Passing Criteria" for the Product- The product "passes" when building tests show no infestation in a minimum of 90% of buildings within the five years following treatment.

Results

FDACS began evaluating the structural data by first reviewing the results from the wooden monitoring stakes installed in 2004. Out of the structures in the study, only structure (No. 29) showed live termite activity in one of the wooden stakes within 10 feet of the structure. Specimens were collected from this stake and identified as Reticulitermes flavipes, a species common to the southeast United States and Florida. For the other buildings, termite activity was identified in wooden debris around, but not within 10 feet, of only 4 structures. \vec{R} .

flavipes was identified in wooden debris near building Nos. 14, 32 and 63, while the species present at structure No. 72 was not identified. The structures with documented termite pressure in the area surrounding the building are identified in the far right-hand column of Table 3.

For the building tests, annual inspections conducted from 2001 through 2003 failed to document infestation in any of the 30 submitted structures. In 2004 but prior to the 2004 annual inspection, Nisus disqualified two structures (Building Nos. 97 and 98) from the study and replaced them with two structures (Nos. 51 and 84) from those remaining in the year 2000 pool. Buildings 97 & 98 were disqualified because both had been treated in 2003 with a soil termiticide in response to termite activity. Nisus was unable to determine whether the infestation was the result of misapplication of Bora-Care or due to product failure. Therefore, Nisus requested and received FDACS approval to remove the structures from the study.

In 2005, Nisus dropped an additional three structures (8uilding Nos. 4, 5, and 75) from the study because the homeowners chose to not renew the annual inspection contract. The structures had completed 4 years of the 5 year study and all were free of infestation at the 2004 annual inspection. These structures were not replaced. At the completion of the fiveyear study, the dataset submitted was comprised of complete (5 years) inspection records for 27 buildings, which is sufficient to satisfy the Rule (Section (2)(c)9). In the 2005 inspection, only one structure (Building No. 90) showed evidence of subterranean termite infestation and received a failing rating.

Table 3 contains construction and treatment details for each structure, as well as, the building inspection results.

Conclusion

Based on the efficacy data from 27 buildings, Bora-Care receives a passing score when evaluated against the performance criteria of the Rule. Specifically, only one of 27 structures (~4%) showed evidence of infestation within the 5 years following treatment with Bora-Care.

SES Summary/Recommendation

Based on the field and structural efficacy data submitted to FDACS, Bora-Care wood-applied termiticide has satisfied all requirements of the Termiticide Efficacy Rule. First, field efficacy trials demonstrated the effectiveness of Bora-Care to prevent tunneling over treated wood and prevent termite damage to an untreated piece of target wood in over 90% of the trials for 5 years. Second, greater than 90% of the buildings in the structural tests remained free of infestation for the 5 years following treatment. This product, therefore, continues to be listed as one of the "Termiticides Registered for Preventive Treatment of New Construction".

Table 3. Bora-Care Building Test Results

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Year 1 Ins	Date	†	5/19/01	1/16/01	11/17/0	1/36/01	10/07/b	10/11/0	10/61/21	10/6//	0/0/0	10/97/1	4/10/01	10/1/6	10/7/4	10/11//	10/07/1	10/12/2	3/11/01	10/07/2	5/3/01	5/17/01	1/3/01	3/5/01	6/11/01	5/31/01	12/20/0	1/11/01	1/30/01		1/11/01	6/9/01	4/3/01	4/30/01	Crawl space Canceled co Termite pre
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